

109TH CONGRESS  
2D SESSION

# S. 2291

To provide for the establishment of a biodefense injury compensation program  
and to provide indemnification for producers of countermeasures.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2006

Mr. KENNEDY (for himself, Mr. DODD, Mr. HARKIN, and Mr. BINGAMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To provide for the establishment of a biodefense injury compensation program and to provide indemnification for producers of countermeasures.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Responsible Public  
5       Readiness and Emergency Preparedness Act”.

6       **SEC. 2. REPEAL.**

7       The Public Readiness and Emergency Preparedness  
8       Act (division C of the Department of Defense, Emergency  
9       Supplemental Appropriations to Address Hurricanes in

1 the Gulf of Mexico, and Pandemic Influenza Act, 2006  
 2 (Public Law 109–148)) is repealed.

3 **SEC. 3. NATIONAL BIODEFENSE INJURY COMPENSATION**  
 4 **PROGRAM.**

5 (a) ESTABLISHMENT.—Section 224 of the Public  
 6 Health Service Act (42 U.S.C. 233) is amended by adding  
 7 at the end the following:

8 “(q) BIODEFENSE INJURY COMPENSATION PRO-  
 9 GRAM.—

10 “(1) ESTABLISHMENT.—There is established  
 11 the Biodefense Injury Compensation Program (re-  
 12 ferred to in this subsection as the ‘Compensation  
 13 Program’) under which compensation may be paid  
 14 for death or any injury, illness, disability, or condi-  
 15 tion that is likely (based on best available evidence)  
 16 to have been caused by the administration of a cov-  
 17 ered countermeasure to an individual pursuant to a  
 18 declaration under subsection (p)(2).

19 “(2) ADMINISTRATION AND INTERPRETA-  
 20 TION.—The statutory provisions governing the Com-  
 21 pensation Program shall be administered and inter-  
 22 preted in consideration of the program goals de-  
 23 scribed in paragraph (4)(B)(iii).

24 “(3) PROCEDURES AND STANDARDS.—The Sec-  
 25 retary shall by regulation establish procedures and

standards applicable to the Compensation Program that follow the procedures and standards applicable under the National Vaccine Injury Compensation Program established under section 2110, except that the regulations promulgated under this paragraph shall permit a person claiming injury or death related to the administration of any covered countermeasure to file either—

“(A) a civil action for relief under subsection (p); or

“(B) a petition for compensation under this subsection.

“(4) INJURY TABLE.—

“(A) INCLUSION.—For purposes of receiving compensation under the Compensation Program with respect to a countermeasure that is the subject of a declaration under subsection (p)(2), the Vaccine Injury Table under section 2114 shall be deemed to include death and the injuries, disabilities, illnesses, and conditions specified by the Secretary under subparagraph (B)(ii).

“(B) INJURIES, DISABILITIES, ILLNESSES, AND CONDITIONS.—

1           “(i) INSTITUTE OF MEDICINE.—Not  
2 later than 30 days after making a declara-  
3 tion described in subsection (p)(2), the  
4 Secretary shall enter into a contract with  
5 the Institute of Medicine, under which the  
6 Institute shall, within 180 days of the date  
7 on which the contract is entered into, and  
8 periodically thereafter as new information,  
9 including information derived from the  
10 monitoring of those who were administered  
11 the countermeasure, becomes available,  
12 provide its expert recommendations on the  
13 injuries, disabilities, illnesses, and condi-  
14 tions whose occurrence in one or more in-  
15 dividuals are likely (based on best available  
16 evidence) to have been caused by the ad-  
17 ministration of a countermeasure that is  
18 the subject of the declaration.

19           “(ii) SPECIFICATION BY SEC-  
20 RETARY.—Not later than 30 days after the  
21 receipt of the expert recommendations de-  
22 scribed in clause (i), the Secretary shall,  
23 based on such recommendations, specify  
24 those injuries, disabilities, illnesses, and  
25 conditions deemed to be included in the

Vaccine Injury Table under section 2114 for the purposes described in subparagraph (A).

“(iii) PROGRAM GOALS.—The Institute of Medicine, under the contract under clause (i), shall make such recommendations, the Secretary shall specify, under clause (ii), such injuries, disabilities, illnesses, and conditions, and claims under the Compensation Program under this subsection shall be processed and decided taking into account the following goals of such program:

“(I) To encourage persons to develop, manufacture, and distribute countermeasures, and to administer covered countermeasures to individuals, by limiting such persons’ liability for damages related to death and such injuries, disabilities, illnesses, and conditions.

“(II) To encourage individuals to consent to the administration of a covered countermeasure by providing adequate and just compensation for

1 damages related to death and such in-  
2 juries, disabilities, illnesses, or condi-  
3 tions.

4 “(III) To provide individuals  
5 seeking compensation for damages re-  
6 lated to the administration of a coun-  
7 termeasure with a non-adversarial ad-  
8 ministrative process for obtaining ade-  
9 quate and just compensation.

10 “(iv) USE OF BEST AVAILABLE EVI-  
11 DENCE.—The Institute of Medicine, under  
12 the contract under clause (i), shall make  
13 such recommendations, the Secretary shall  
14 specify, under clause (ii), such injuries,  
15 disabilities, illnesses, and conditions, and  
16 claims under the Compensation Program  
17 under this subsection shall be processed  
18 and decided using the best available evi-  
19 dence, including information from adverse  
20 event reporting or other monitoring of  
21 those individuals who were administered  
22 the countermeasure, whether evidence from  
23 clinical trials or other scientific studies in  
24 humans is available.

1                   “(v)   APPLICATION   OF   SECTION  
 2                   2115.—With respect to section 2115(a)(2)  
 3                   as applied for purposes of this subsection,  
 4                   an award for the estate of the deceased  
 5                   shall be—

6                   “(I) if the deceased was under  
 7                   the age of 18, an amount equal to the  
 8                   amount that may be paid to a sur-  
 9                   vivor or survivors as death benefits  
 10                  under the Public Safety Officers’ Ben-  
 11                  efits Program under subpart 1 of part  
 12                  L of title I of the Omnibus Crime  
 13                  Control and Safe Streets Act of 1968  
 14                  (42 U.S.C. 3796 et seq.); or

15                  “(II) if the deceased was 18  
 16                  years of age or older, the greater of—

17                       “(aa) the amount described  
 18                       in subclause (I); or

19                       “(bb) the projected loss of  
 20                       employment income, except that  
 21                       the amount under this item may  
 22                       not exceed an amount equal to  
 23                       400 percent of the amount that  
 24                       applies under item (aa).

1 “(vi) APPLICATION OF SECTION  
 2 2116.—Section 2116(b) shall apply to in-  
 3 juries, disabilities, illnesses, and conditions  
 4 initially specified or revised by the Sec-  
 5 retary under clause (ii), except that the ex-  
 6 ceptions contained in paragraphs (1) and  
 7 (2) of such section shall not apply.

8 “(C) RULE OF CONSTRUCTION.—Section  
 9 13632 (a)(3) of Public Law 103–66 (107 Stat.  
 10 646) (making revisions by Secretary to the Vac-  
 11 cine Injury Table effective on the effective date  
 12 of a corresponding tax) shall not be construed  
 13 to apply to any revision to the Vaccine Injury  
 14 Table made under regulations under this para-  
 15 graph.

16 “(5) APPLICATION.—The Compensation Pro-  
 17 gram applies to any death or injury, illness, dis-  
 18 ability, or condition that is likely (based on best  
 19 available evidence) to have been caused by the ad-  
 20 ministration of a covered countermeasure to an indi-  
 21 vidual pursuant to a declaration under subsection  
 22 (p)(2).

23 “(6) SPECIAL MASTERS.—

24 “(A) HIRING.—In accordance with section  
 25 2112, the judges of the United States Claims



1 Court shall appoint a sufficient number of spe-  
2 cial masters to address claims for compensation  
3 under this subsection.

4 “(B) BUDGET AUTHORITY.—There are ap-  
5 propriated to carry out this subsection such  
6 sums as may be necessary for fiscal year 2006  
7 and each fiscal year thereafter. This subpara-  
8 graph constitutes budget authority in advance  
9 of appropriations and represents the obligation  
10 of the Federal Government.

11 “(7) COVERED COUNTERMEASURE.—For pur-  
12 poses of this subsection, the term ‘covered counter-  
13 measure’ has the meaning given to such term in sub-  
14 section (p)(7)(A).

15 “(8) FUNDING.—Compensation made under the  
16 Compensation Program shall be made from the same  
17 source of funds as payments made under subsection  
18 (p).”.

19 (b) EFFECTIVE DATE.—This section shall take effect  
20 as of November 25, 2002 (the date of enactment of the  
21 Homeland Security Act of 2002 (Public Law 107–296;  
22 116 Stat. 2135)).

1 **SEC. 4. INDEMNIFICATION FOR MANUFACTURERS AND**  
 2 **HEALTH CARE PROFESSIONALS WHO ADMIN-**  
 3 **ISTER MEDICAL PRODUCTS NEEDED FOR**  
 4 **BIODEFENSE.**

5 Section 224(p) of the Public Health Service Act (42  
 6 U.S.C. 233(p)) is amended—

7 (1) in the subsection heading by striking  
 8 “SMALLPOX”;

9 (2) in paragraph (1), by striking “against  
 10 smallpox”;

11 (3) in paragraph (2)—

12 (A) in the paragraph heading, by striking  
 13 “AGAINST SMALLPOX”; and

14 (B) in subparagraph (B), by striking  
 15 clause (ii);

16 (4) by striking paragraph (3) and inserting the  
 17 following:

18 “(3) EXCLUSIVITY; OFFSET.—

19 “(A) EXCLUSIVITY.—With respect to an  
 20 individual to which this subsection applies, such  
 21 individual may bring a claim for relief under—

22 “(i) this subsection;

23 “(ii) subsection (q); or

24 “(iii) part C.

25 “(B) ELECTION OF ALTERNATIVES.—An  
 26 individual may only pursue one remedy under

1           subparagraph (A) at any one time based on the  
2           same incident or series of incidents. An indi-  
3           vidual who elects to pursue the remedy under  
4           subsection (q) or part C may decline any com-  
5           pensation awarded with respect to such remedy  
6           and subsequently pursue the remedy provided  
7           for under this subsection. An individual who  
8           elects to pursue the remedy provided for under  
9           this subsection may not subsequently pursue  
10          the remedy provided for under subsection (q) or  
11          part C.

12                 “(C) STATUTE OF LIMITATIONS.—For pur-  
13           poses of determining how much time has lapsed  
14           when applying statute of limitations require-  
15           ments relating to remedies under subparagraph  
16           (A), any limitation of time for commencing an  
17           action, or filing an application, petition, or  
18           claim for such remedies, shall be deemed to  
19           have been suspended for the periods during  
20           which an individual pursues a remedy under  
21           such subparagraph.

22                 “(D) OFFSET.—The value of all compensa-  
23           tion and benefits provided under subsection (q)  
24           or part C of this title for an incident or series  
25           of incidents shall be offset against the amount

of an award, compromise, or settlement of money damages in a claim or suit under this subsection based on the same incident or series of incidents.”;

(5) in paragraph (6)—

(A) in subparagraph (A), by inserting “or under subsection (q) or part C” after “under this subsection”; and

(B) by redesignating subparagraph (B) as subparagraph (C);

(C) by inserting after subparagraph (A), the following:

“(B) GROSSLY NEGLIGENT, RECKLESS, OR ILLEGAL CONDUCT AND WILLFUL MISCONDUCT.—For purposes of subparagraph (A), grossly negligent, reckless, or illegal conduct or willful misconduct shall include the administration by a qualified person of a covered countermeasure to an individual who was not within a category of individuals covered by a declaration under subsection (p)(2) with respect to such countermeasure where the qualified person fails to have had reasonable grounds to believe such individual was within such a category.”; and

(D) by adding at the end the following:

1           “(D)   LIABILITY   OF   THE   UNITED  
2   STATES.—The United States shall be liable  
3   under this subsection with respect to a claim  
4   arising out of the manufacture, distribution, or  
5   administration of a covered countermeasure re-  
6   gardless of whether—

7           “(i) the cause of action seeking com-  
8           pensation is alleged as negligence, strict li-  
9           ability, breach of warranty, failure to warn,  
10          or other action; or

11          “(ii) the covered countermeasure is  
12          designated as a qualified anti-terrorism  
13          technology under the SAFETY Act (6  
14          U.S.C. 441 et seq.).”

15          “(E) GOVERNING LAW.—Notwithstanding  
16   the provisions of section 1346(b)(1) and chap-  
17   ter 171 of title 28, United States Code, as they  
18   relate to governing law, the liability of the  
19   United States as provided in this subsection  
20   shall be in accordance with the law of the place  
21   of injury.

22          “(F) MILITARY PERSONNEL AND UNITED  
23   STATES CITIZENS OVERSEAS.—

24          “(i) MILITARY PERSONNEL.—The li-  
25          ability of the United States as provided in

1           this subsection shall extend to claims  
2           brought by United States military per-  
3           sonnel.

4           “(ii) CLAIMS ARISING IN A FOREIGN  
5           COUNTRY.—Notwithstanding the provisions  
6           of section 2680(k) of title 28, United  
7           States Code, the liability of the United  
8           States as provided for in the subsection  
9           shall extend to claims based on injuries  
10          arising in a foreign country where the in-  
11          jured party is a member of the United  
12          States military, is the spouse or child of a  
13          member of the United States military, or is  
14          a United States citizen.

15          “(iii) GOVERNING LAW.—With regard  
16          to all claims brought under clause (ii), and  
17          notwithstanding the provisions of section  
18          1346(b)(1) and chapter 171 of title 28,  
19          United States Code, and of subparagraph  
20          (C), as they relate to governing law, the li-  
21          ability of the United States as provided in  
22          this subsection shall be in accordance with  
23          the law of the claimant’s domicile in the  
24          United States or most recent domicile with  
25          the United States.”; and

1 (6) in paragraph (7)—

2 (A) by striking subparagraph (A) and in-  
3 serting the following:

4 “(A) COVERED COUNTERMEASURE.—The  
5 term ‘covered countermeasure’, means—

6 “(i) a substance that is—

7 “(I)(aa) used to prevent or treat  
8 smallpox (including the vaccinia or  
9 another vaccine); or

10 “(bb) vaccinia immune globulin  
11 used to control or treat the adverse  
12 effects of vaccinia inoculation; and

13 “(II) specified in a declaration  
14 under paragraph (2); or

15 “(ii) a drug (as such term is defined  
16 in section 201(g)(1) of the Federal Food,  
17 Drug, and Cosmetic Act), biological prod-  
18 uct (as such term is defined in section  
19 351(i) of this Act), or device (as such term  
20 is defined in section 201(h) of the Federal  
21 Food, Drug, and Cosmetic Act) that—

22 “(I) the Secretary determines to  
23 be a priority (consistent with sections  
24 302(2) and 304(a) of the Homeland  
25 Security Act of 2002) to treat, iden-

1           tify, or prevent harm from any bio-  
2           logical, chemical, radiological, or nu-  
3           clear agent identified as a material  
4           threat under section 319F-  
5           2(c)(2)(A)(ii), or to treat, identify, or  
6           prevent harm from a condition that  
7           may result in adverse health con-  
8           sequences or death and may be caused  
9           by administering a drug, biological  
10          product, or device against such an  
11          agent;

12               “(II) is—

13                   “(aa) authorized for emer-  
14                   gency use under section 564 of  
15                   the Federal Food, Drug, and  
16                   Cosmetic Act, so long as the  
17                   manufacturer of such drug, bio-  
18                   logical product, or device has—

19                           “(AA) made all reason-  
20                           able efforts to obtain appli-  
21                           cable approval, clearance, or  
22                           licensure; and

23                           “(BB) cooperated fully  
24                           with the requirements of the



1 Secretary under such section  
2 564; or

3 “(bb) approved or licensed  
4 solely pursuant to the regulations  
5 under subpart I of part 314 or  
6 under subpart H of part 601 of  
7 title 21, Code of Federal Regula-  
8 tions (as in effect on the date of  
9 enactment of the National Bio-  
10 defense Act of 2005); and

11 “(III) is specified in a declaration  
12 under paragraph (2).”; and

13 (B) in subparagraph (B)—

14 (i) by striking clause (ii), and insert-  
15 ing the following:

16 “(ii) a health care entity, a State, or  
17 a political subdivision of a State under  
18 whose auspices such countermeasure was  
19 administered;” and

20 (vi) in clause (viii), by inserting before  
21 the period “if such individual performs a  
22 function for which a person described in  
23 clause (i), (ii), or (iv) is a covered person”.

○